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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,705	03/30/2004	J. Richard Gyory	ALZA-0377/ALZ5016USANP	7214

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EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
06/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,705	GYORY, J. RICHARD	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/21/2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 3/30/2007.

2. In the reply, the applicant amended claim 1; cancelled claim 4.

3. Thus, claims 1-3, 5-16 are pending for examination.

4. Additionally, the Applicant argues against the objections to the drawings for introducing new matter into the application. The Applicant's arguments are not persuasive (See discussion below in "Specification").

Specification

5. The amendment filed 10/19/2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The submission of newly added Figure 5 showing the device depicted in Figure 4, in addition to a power source (150) and an active agent reservoir (160) containing an active agent (165), is an introduction of new matter because the result of disclosure of newly added Figure 5 changes the metes and bounds of the invention beyond what was originally disclosed in the specification when originally filed. For instance, the metes and bounds of the Applicant's invention can now seek to claim, for instance, any physical relationship between elements shown and pictured in Figure 5. Consider the Applicant's originally disclosed description (paragraph 31): "Electrical coating 104 would therefore be in contact with the agent containing reservoir that would be placed within reservoir housing

120." Now, Figure 5 shows and allows the Applicant to further define the metes and bounds of their invention to include such claim limitations as the electrical coating contacts the agent containing reservoir on its top side and is substantially spaced downwardly from the top surface of the reservoir housing. Claim limitations of this type are fully capable of being put forth based solely on the disclosure of Figure 5 and do not originate from the Applicant's original disclosure. Thus, newly added Figure 5 introduces new matter into the disclosure of the invention.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-6 rejected under 35 U.S.C. 102(b) as being anticipated by Flower (5857994). Flower discloses an electrotransport device (Fig 1) having a first (8) electrode, the first electrode in communication with a first reservoir (14) adapted to receive an active agent formulation that is a therapeutic agent (12; Summary), a power source (22) in communication with electronic circuitry (24) in communication with first electrodes (8), a non-conductive reservoir housing (4) having an internal cavity (Fig 1-2)

containing said first electrode (8) and first reservoir (14) and the reservoir housing having an electrically conductive element (8, 26; Fig 1-2) integrally molded within the non-conductive housing and that is substantially planar (26, Fig 1), flexible (26; Fig 1; col 4, lns 25-31, 38-41), with a conductive coating (26; Fig 1, col 4, lns 28-31) and that has a first end in communication with the first reservoir (Fig 1-2) and a second end that is disposed on the outside of the reservoir housing (Fig 1-2) and extending therefrom to be operatively connected to the power source through the electronic circuitry (Figs 1-5; col 4, lns 15-col 5, lns 50).

8. Claims 1-11, 15-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuribayashi et al (6915159). Kuribayashi et al discloses an electrotransport device (Figs 1-12) having a first (2) electrode, the first electrode in communication with a first reservoir (20, 12) adapted to receive an active agent formulation that is a therapeutic agent (20, col 9, lns 42-col 10, lns 46), a power source (1d, Fig 8) in communication with electronic circuitry (18, Fig 8) in communication with first electrodes (2), a non-conductive reservoir housing (1) having an internal cavity (Fig 1, 6) containing said first electrode (2) and first reservoir (12, 20) and the reservoir housing having an electrically conductive element (2) integrally molded within the non-conductive housing and that is substantially planar (2, Fig 1, 6), flexible (2, Fig 1,6), with a conductive coating (col 7, lns 1-5, 39-47) and that has a first end in communication with the first reservoir (Fig 1, 6) and a second end that is disposed on the outside of the reservoir housing (Fig 1, 6, 2,

14, 15, 17) and extending therefrom to be operatively connected to the power source through the electronic circuitry (Fig 1, 6, 8-11).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuribayashi et al. Kuribayashi et al discloses the invention substantially as claimed except for expressly disclosing wherein the active agent formulation includes a therapeutic agent being the specific agents disclosed in the applicant's claims 12-14. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the therapeutic agent being the specific agents disclosed in the applicant's claims 12-14 because the Applicant has not disclosed that having the therapeutic agent being the specific agents disclosed in the applicant's claims 12-14 provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with therapeutic agents of Kuribayashi et al because the Applicant has not given any criticality for the therapeutic agents being the specifically claimed agents. Therefore, it would have been an obvious

matter of design choice to modify Linkwitz et al to obtain the invention as specified in claims 12-14.

Response to Arguments

11. Applicant's arguments filed 3/30/2007 have been fully considered but they are not persuasive.

12. The Applicant argues that:

i. Flower does not disclose the patch having a housing having an internal cavity that contains the electrodes, that the interconnectors are integrally molded within a housing, and that the conductive element is substantially flexible. (Remarks, pg 7, paragraph 3)

ii. Kuribayshi does not disclose a non-conductive reservoir housing having an internal cavity containing a first electrode and a 1st reservoir including a substantially flexible electrically conductive element integrally molded within the housing and that the conductive element has a first end in communication with the 1st reservoir and a second end that is disposed on the outside of the reservoir housing and extends therefrom. (Remarks, pg 8, paragraph 2)

13. In response to the Applicant's argument (i), the Examiner notes that Flower does disclose the patch having a housing (4) having an internal cavity (4; Fig 1 and 2) that contains the electrodes (8, Fig 1, 2; wherein the Examiner notes that it is clearly shown by the housing encloses the electrode (8) in a cavity that houses both the reservoir and drug (14 and 12) as well as the electrode (8) and it is shown in Fig 2 that the housing (4)

clearly covers the top portion of the electrode (8)), that the interconnectors are integrally molded within a housing (26, 34, Fig 1; wherein the electrical connecting portions (26, 34) are integrally molded in the housing), and that the conductive element is substantially flexible (26; Fig 1; col 4, lns 25-31, 38-41; wherein the Examiner notes that it is clear that the patch is flexible and that the electrical conductive elements (26) are integrally housed within the flexible housing and are themselves disclosed as being substantially flexible printed circuits, foils, wires, etc...). The rejection is maintained.

14. In response to the Applicant's argument (ii), the Examiner notes Kuribayshi does disclose a non-conductive reservoir housing (1) having an internal cavity (5; Fig 1c) containing a first electrode (2) and a 1st reservoir (12) including a substantially flexible electrically conductive element (col 6, lns 34-39; col 7, lns 15-23; wherein it is disclosed that the housing is substantially flexible, but not beyond a limit, to allow the conductive elements to flex but not be physically destroyed while allowing conformation to the patient's skin. Thus, it is clear to one of ordinary skill in the art that the housing and conductive elements are both substantially flexible) integrally molded within the housing and that the conductive element has a first end in communication with the 1st reservoir (2, area of 5, Fig 1c, 10a, 10b) and a second end that is disposed on the outside of the reservoir housing and extends therefrom (2, "1cm No 1.", Fig 10a, b; and Figs 1, 6, 8-11). The rejection is maintained.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER